

Office of the Secretary
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Robert Moser, MD, Secretary

Department of Health & Environment

Sam Brownback, Governor

November 21, 2011

Barbara Dominguez
Office of the Secretary of State
120 SW 10th St.
Topeka KS 66612

RE: Filing Notice of Hearing for Proposed Administrative Regulations
KAR 28-54-1, 28-54-2, 28-54-3, 28-54-4 and 28-54-5

Dear Ms. Dominguez:

Attached are two copies of the above-referenced Kansas Department of Health and Environment proposed amended permanent Article 54 regulations concerning designation of trauma centers. Two copies of the economic impact statement are also included.

Also attached are two copies of the notice of public hearing for this regulation. The public hearing is scheduled for February 9, 2012, at 10:00 a.m. in the Flint Hills Conference Rm., Curtis State Office Bldg., Topeka. Please cause the notice of public hearing to be published in the *Kansas Register*.

If you have any questions or need any further information regarding filing of the notice of hearing for this regulation, please contact Susan Vogel at 296-1291 or svogel@kdheks.gov.

Sincerely,

Robert Moser, MD
Secretary of Health and Environment

Attachments

pc w/notice of hearing only
Rep. Carl Holmes, Chair, Joint Committee on Rules and Regulations
Sen. Vicki Schmidt, Vice Chair, Joint Committee on Rules and Regulations
Rep. Janice Pauls, Ranking Minority Member, Joint Committee on Rules and Regulations
Raney Gilliland, Legislative Research

STATE OF KANSAS
Department of Health and Environment

Notice of Hearing on Proposed Administrative Regulations

The Kansas Department of Health and Environment, Division of Health, Bureau of Local and Rural Health, will conduct a public hearing at 10 a.m. Thursday, February 9, in the Flint Hills Conference Room, third floor of the Curtis State Office Building, 1000 S.W. Jackson, Topeka, to consider the adoption of proposed amended regulations K.A.R. 28-54-1, 28-54-2, 28-54-3, 28-54-4, and 28-54-5 concerning designation of hospitals as trauma centers. A summary of the proposed regulations and the estimated economic impact follows:

Summary of the Regulations:

28-54-1. Defines the terms used in the trauma center regulations and updates the regulation to include the definition of level IV trauma center and references to level IV trauma center in existing definitions as necessary.

28-54-2. Specifies the requirements by which a hospital is designated as a level I, level II, or level III trauma center and updates the regulation to include the requirements for designation of a hospital as a level IV trauma center.

28-54-3. Establishes the application process by which a hospital can apply for designation as a level I, level II, or level III trauma center and updates the regulation to include the application process for a level IV trauma center.

28-54-4. Establishes the process by which a hospital can request a change of designation to a level I, level II, or level III trauma center and updates the regulation to include the application process for change to designation to a level IV trauma center.

28-54-5. Specifies the period of time for which a certificate of designation as a trauma center is valid and provides for the process of renewal of a certificate of designation as a level I, level II, or level III trauma center and updates the regulation to include renewal of a certificate of designation as a level IV trauma center.

Economic Impact:

Cost to individuals: The goal of a trauma center as part of a larger trauma system is to improve efficiency, decrease health care costs, improve patient outcomes and reduce death and disability. Designation of trauma centers would ultimately decrease health care costs for consumers and the state of Kansas through efficiency of service and evidence-based standards of care. When hospitals serve as designated trauma centers, federal guidelines allow hospitals to bill insurance carriers, commercial and public, for providing trauma team services as part of a trauma system.

Cost to the agency: As part of the implementation process, KDHE will incur expenses related to processing of applications. If a site survey is conducted, the agency will incur expenses for the on-site survey process. Current staff within the trauma program will be utilized to process and review level IV applications. The Advisory Committee on Trauma can be utilized as a resource to assist with on-site surveys. The Trauma Fee Fund will be utilized to pay travel and honorarium expenses related to non-KDHE survey team members if needed.

Cost to other governmental agencies or units: Having designated trauma centers in Kansas will help in emergency preparedness situations, which will benefit other agencies. When an emergency response is needed, knowing the trauma care resources within a region or state will help in triaging patients to the closest appropriate facility saving time, resources and

transportation expenses. There is no known increase in costs to other governmental agencies or units.

The time period between the publication of this notice and the scheduled hearing serves as the required public comment period of at least 60 days for the purpose of receiving written public comments on the proposed regulatory action. All interested parties may submit written comments prior to 5 p.m. on the day of the hearing to Rosanne Rutkowski, Kansas Department of Health and Environment, Bureau of Local and Rural Health, 1000 SW Jackson, Suite 340, Topeka, 66612, by fax to (785) 296-1231, or by e-mail to rrutkowski@kdheks.gov. During the hearing, all interested parties will be given a reasonable opportunity to present their views orally on the proposed regulatory action as well as an opportunity to submit their written comments. In order to give all parties an opportunity to present their views, it may be necessary to require each participant to limit any oral presentation to five minutes.

Copies of the proposed regulations and the corresponding economic impact statement may be obtained on the KDHE Web site at www.kstrauma.org or by contacting Rosanne Rutkowski at (785) 296-1210 or rrutkowski@kdheks.gov. Questions pertaining to the proposed regulations should be directed to Rosanne Rutkowski.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the proposed regulations and the corresponding economic impact statement in an accessible format. Requests for accommodation to participate in the hearing should be made at least five working days in advance of the hearing by contacting Rosanne Rutkowski.

Robert Moser, MD

Secretary of Health and Environment

28-54-1. Definitions. Each of the following terms used in this article shall have the meaning specified in this regulation:

(a) "ACS" means American college of surgeons.

(b) "Department" means the Kansas department of health and environment.

(c) "Designation" means a determination by the secretary that a hospital shall provide the trauma care required of a level I trauma center, level II trauma center, ~~or~~ level III trauma center, or level IV trauma center.

(d) "Level I trauma center" means a hospital that has the capability to provide the highest level of trauma care for every aspect of injury, from prevention through rehabilitation.

(e) "Level II trauma center" means a hospital that meets the following conditions:

(1) Provides initial trauma care, regardless of the severity of the injury;

(2) is not necessarily able to provide the same comprehensive care as that provided by a level I trauma center; and

(3) does not have trauma research as a primary objective.

(f) "Level III trauma center" means a hospital that provides initial trauma care or arranges for the appropriate transfer of trauma patients to a level I trauma center or a level II trauma center.

(g) "Level IV trauma center" means a hospital that provides urgent care for injured persons and the timely transfer of the seriously injured to a level I trauma center, level II trauma center, or level III trauma center as appropriate.

(h) "Regional trauma council" means one of the six councils, as defined in K.S.A. 75-5663 and amendments thereto, in the state established to address trauma and emergency medical

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care issues within a specific geographic area and to coordinate services to meet the needs of trauma patients injured within that area.

~~(h)~~ (i) "Trauma" means any of the following:

(1) Any injury to a person that results from acute exposure to mechanical, thermal, electrical, or chemical energy;

(2) any injury to a person that is caused by the absence of heat or oxygen and that requires immediate medical intervention; or

(3) any injury to a person that requires surgical intervention or treatment to prevent death or permanent disability.

~~(i)~~ (j) "Trauma facility" means a hospital distinguished by the availability of surgeons, physician specialists, anesthesiology services, nurses, and resuscitation and life-support equipment on a 24-hour basis to care for persons with trauma. This term shall include the following:

(1) Level I trauma centers;

(2) level II trauma centers; ~~and~~

(3) level III trauma centers; ~~and~~

(4) level IV trauma centers.

~~(j)~~ (k) "Trauma registry" means the database maintained and operated by the department to collect and analyze reportable patient data on the incidence, severity, and causes of trauma.

~~(k)~~ (l) "Verification" means the process by which the American college of surgeons confirms a hospital's trauma care capability and performance. (Authorized by K.S.A. 2006 2010)

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Supp. 75-5665, as amended by L. 2011, ch. 114, sec. 38; implementing K.S.A. 2006 2010 Supp.
75-5665, as amended by L. 2011, ch. 114, sec. 38, and K.S.A. 2006 2010 Supp. 75-5666;
effective Nov. 2, 2007; amended P-_____.)

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28-54-2. Standards for designation. The designation of a hospital as a level I trauma center, level II trauma center, ~~or level III trauma center,~~ or level IV trauma center shall be made by the secretary based on the capability of the hospital to meet the requirements of the requested designation, as specified in this regulation:

(a) For level I trauma centers and level II trauma centers, verification by the American college of surgeons that the hospital meets the standards specified in the “resources for optimal care of the injured patient: 2006,” excluding the appendices, published by the American college of surgeons, which is adopted by reference, or a determination by the secretary that the hospital meets equivalent standards; ~~and~~

(b) for level III trauma centers, the “Kansas trauma care facility categorization criteria for level III trauma ~~centers~~ center,” published by the Kansas ~~trauma program and the~~ advisory committee on trauma and dated April 6, 2007, which is adopted by reference; and

(c) for level IV trauma centers, the “Kansas trauma care facility categorization criteria for level IV trauma center,” published by the Kansas advisory committee on trauma and dated August 25, 2010, which is adopted by reference. (Authorized by and implementing K.S.A. 2006 2010 Supp. 75-5665, as amended by L. 2011, ch. 114, sec. 38; effective Nov. 2, 2007; amended P-_____.)

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28-54-3. Application for designation. (a)(1) Each hospital administrator that seeks a certificate of designation for its hospital shall submit the following to the secretary:

(A) A designation application on a form provided by the department, ~~which. Each applicant seeking designation as a level I trauma center, level II trauma center, or level III trauma center shall include one of the following:~~

- (i) A copy of the applicant's current ACS verification certificate; or
- (ii) documentation of successful completion of the secretary's on-site survey; and

(B) a one of the following nonrefundable application fee of fees:

(i) \$500 for designation as a level I trauma center, level II trauma center, or level III trauma center; or

(ii) \$250 for designation as a level IV trauma center.

(2) An application shall not be deemed complete until all of the required materials have been received. Each applicant shall be notified by the department of the completeness of the application within 30 days after the application is submitted to the department.

(b) Any applicant seeking designation of its hospital as a level III trauma center may request an on-site survey from the department by submitting a request with the application. The applicant shall be notified by the department of the date on which the on-site survey is scheduled and the amount of the nonrefundable fee for the on-site survey, which shall not exceed \$15,000. The applicant shall submit this fee at least 30 days before the date of the on-site survey.

(c) For each hospital seeking a level IV designation, a site visit may be arranged before the three-year designation period, within the three-year designation period, and every three years thereafter to coincide with the three-year designation process.

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(d) The findings of the on-site survey team shall be provided to each applicant within 60 calendar days after the date of each survey. If a hospital does not meet the requirements for the level of designation for which the hospital administrator has applied, the hospital administrator shall be notified of the requirements that the hospital is required to meet for designation at the requested level. The hospital administrator shall submit to the secretary a plan of the proposed actions that the hospital will take to ensure compliance with the requirements. A second survey may be required by the secretary. The secretary's survey team shall make a recommendation for the designation to the secretary, based on the hospital's capability to meet the criteria for the requested level of designation.

~~(d)~~ (e) Each applicant specified in subsection ~~(e)~~ (d) shall be notified by the secretary about the status of designation as a trauma facility within 90 calendar days after the applicant's last survey.

~~(e)~~ (f) Each applicant who submits a current ACS one-year or three-year verification certificate with an application and the required fee shall be notified by the secretary about the status of designation as a trauma facility within 30 calendar days after these required materials are submitted to the secretary.

~~(f)~~ (g) Each certificate of designation shall be valid from the date of issuance and for the period of time specified on the certificate. (Authorized by and implementing K.S.A. 2006 2010 Supp. 75-5665, as amended by L. 2011, ch. 114, sec. 38; effective Nov. 2, 2007; amended

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28-54-4. Application for change of designation. (a) Any administrator of a designated trauma facility may request a change of designation by submitting the following to the secretary:

(1) An application for a change of designation on the form provided by the department, ~~which shall include one.~~ Each applicant seeking a change of designation to a level I trauma center, level II trauma center, or level III trauma center shall include one of the following:

(A) A copy of the applicant's current ACS verification certificate for the level of designation sought; or

(B) documentation of successful completion of the secretary's on-site survey for the level of designation sought. The applicant may request an on-site survey from the department by submitting a request with the application; and

(2) ~~the one of the following nonrefundable fee of fees:~~

(A) \$500 for designation as a level I trauma center, level II trauma center, or level III trauma center; or

(B) \$250 for designation as a level IV trauma center.

An application shall not be deemed complete until all of the required materials have been received. Each applicant shall be notified by the department of the completeness of the application within 30 calendar days after the application is submitted to the department.

(b) If the applicant seeking designation of its hospital as a level III trauma center requests an on-site survey by the department, the applicant shall be notified by the department of the date on which the on-site survey is scheduled and the amount of the nonrefundable fee for the on-site survey, which shall not exceed \$15,000. The applicant shall submit this fee at least 30 calendar days before the date of the on-site survey.

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(c) The findings of the secretary's on-site survey team shall be provided to the applicant within 60 calendar days after the date of the survey. The survey team shall make a recommendation for the designation to the secretary, based on the hospital's capability to meet the criteria for the requested level of designation.

(d) Each applicant specified in subsection (c) shall be notified by the secretary about the status of designation as a trauma facility within 90 calendar days after the applicant's on-site survey.

(e) Each applicant who submits a current ACS one-year or three-year verification certificate for the level of designation sought with an application and the required fee shall be notified by the secretary about the status of designation as a trauma facility within 30 calendar days after these required materials are submitted to the secretary.

(f) Each change of designation certificate shall be valid from the date of issuance and for the period specified on the certificate. (Authorized by and implementing K.S.A. ~~2006~~ 2010 Supp. 75-5665, as amended by L. 2011, ch. 114, sec. 38; effective Nov. 2, 2007; amended P-_____.)

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28-54-5. Certificate of designation; renewal. (a) Each certificate of designation shall be valid for three years from the effective date specified on the certificate.

(b)(1) Each administrator of a designated trauma facility that wants to renew the trauma facility's certificate of designation shall submit the following at least six months before the expiration date specified on the certificate of designation:

(A) An application for renewal of the hospital's designation on a form provided by the department, which shall include the following:

(i) A copy of the applicant's current ACS verification certificate; or

(ii) documentation of successful completion of the secretary's on-site survey. If an applicant for renewal wants to request an on-site survey from the department, the applicant shall meet the requirements specified in K.A.R. 28-54-3(b) and or (c) and in K.A.R. 28-54-3(d); and

(B) a one of the following nonrefundable renewal fee of fees:

(i) \$500 for designation as a level I trauma center, level II trauma center, or level III trauma center; or

(ii) \$250 for designation as a level IV trauma center.

(2) An application shall not be deemed complete until all of the required materials have been received. Each applicant for renewal shall be notified by the department of the completeness of the application within 30 calendar days after the application is submitted to the department. Except as otherwise provided in subsection (c), failure to renew the certificate of designation before the expiration date shall render the certificate invalid.

(c) The certificate of designation shall not expire on the specified expiration date if all of the required materials specified in paragraph (b)(1) have been submitted to the secretary at least

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six months before the expiration date on the certificate of designation. In this case, the certificate of designation shall expire on the earlier of the following dates:

(1) The date on which the certificate of designation is renewed; or

(2) the date on which the secretary denies the renewal application. (Authorized by and implementing K.S.A. 2006 2010 Supp. 75-5665, as amended by L. 2011, ch. 114, sec. 38; effective Nov. 2, 2007; amended P-_____.)

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Date: November 21, 2011

Kansas Department of Health and Environment
Economic Impact Statement

Pursuant to the requirements of KSA 77-416, Kansas Department of Health and Environment submits the following economic impact statement.

1. Regulation(s):

K.A.R. 28-54-1

K.A.R. 28-54-2

K.A.R. 28-54-3

K.A.R. 28-54-4

K.A.R. 28-54-5

2. Brief description of each regulation(s) and what is intended to be accomplished by adoption.

28-54-1. Provides definition of terms used in the trauma center regulations and updates the regulation to include definition for level IV trauma center.

28-54-2. Specifies the requirement by which a hospital is designated as a level I, level II, level III or level IV trauma center. Defines the standards by which a hospital is designated as a trauma center.

28-54-3. Establishes the application process by which a hospital can apply for designation as a level I, level II, level III trauma center and updates the regulation to include level IV trauma center designation.

28-54-4. Defines the application process by which a hospital can request a change of designation for a level I, level II, level III trauma center and updates the regulation to include the application process for change to designation as a level IV trauma center.

28-54-5. Specifies the period of time for which a certificate of designation as a trauma center is valid and provides for the process of renewal of a certificate of designation for a level I,

level II, level III trauma center and updates the regulation to include a renewal of a certificate of designation as a level IV trauma center.

3. **Is this regulation(s) mandated by federal law as a requirement for participating in or implementing a federally subsidized or assisted program?**

Yes _____

No x

If yes, please explain.

4. **Do the proposed regulations exceed the requirements of applicable federal law?**

Yes _____

No x

If yes, please explain.

5. **Description of Costs:**

a. Cost to the agency:

It is anticipated that the costs incurred by KDHE to implement these regulations will be minimal. To decrease costs associated with processing of level IV applications, KDHE will design their application forms so they can be easily accessed and/or completed on line and submitted electronically to KDHE. Current staff within the trauma program will be utilized to process and review level IV applications. Staff will also coordinate any on site surveys performed. Physician and nurse representatives from the Advisory Committee on Trauma and/or physician members of the American College of Surgeons (ACS) state committee will be utilized to assist as part of the survey team. The trauma fee fund will be used to help with survey team expenses such as travel and honorariums to ACT members.

Cost to persons who will bear the costs and those who will be affected,(i.e. private citizens and consumers of the products or services) and are subject to the proposed rules and regulations or the enforcement:

The goal of a trauma center as part of a larger trauma system is to improve efficiency, decrease health care costs, improve patient outcomes and reduce death and disability. Designation of trauma centers would ultimately decrease health care costs for consumers and the state of Kansas through efficiency of service and evidence based standards of care. When hospitals serve as designated trauma centers, federal guidelines allow hospitals to bill insurance carriers (commercial & public) for providing trauma team services as part of a trauma system. As such, designated trauma centers have the potential to bill for and recoup some of their costs related to the care of the injured.

b. Costs to other governmental agencies or units:

There is no known increase in costs to other governmental agencies or units. Having designated trauma centers in Kansas would be of great benefit to other agencies such as disaster management/emergency preparedness. When an emergency response is needed, knowing the trauma care resources in the state or region will help in triaging patients to the closest appropriate trauma center thereby reserving medical resources for those most in need and promoting efficient use of transportation resources.

6. Description of any less costly or less intrusive methods that were considered by the agency for the purpose of the rules and regulations and why such methods were rejected in favor of the proposed rules and regulations.

The regulations as written by KDHE are designed to be consistent with current state and national standards for trauma system care.

7. Verification of economic impact statement with League of Kansas Municipalities, Kansas Association of Counties and the Kansas Association of School Boards.

The above mentioned regulations were determined as appropriate for consultation as to the economic impact with the League of Kansas Municipalities, Kansas Association of Counties and the Kansas Association of School Boards, pursuant to KSA 77-416.

Yes _____

No ☒ x

If yes:

Date Contacted and by what means (i.e., letter, FAX, etc.):

Response and comments received by:

League of Kansas Municipalities:

Kansas Association of Counties:

Kansas Association of School Boards: